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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte BRETT T. HAARALA and ARTHUR DRISCOLL

Appeal 2008-1970
Application 09/838,618
Technology Center 3700

Decided: April 30, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

The following claims are representative.

43. A medical device comprising:

an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and

a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.

44. A medical device according to claim 43, wherein the compound slit is disposed on a distal end of the elongate catheter.

45. A medical device according to claim 44, further comprising a collar disposed at the distal end of the catheter.

46. A medical device according to claim 43, wherein the compound slit is a tricuspid slit.

61. A medical device according to claim 43, wherein the compound slit is configured so that, when the fluid pressure within the lumen exceeds the fluid pressure outside the catheter by a first predetermined amount, flaps of the hemispherical portion formed by the compound slit flex outward away from a longitudinal axis of the catheter to allow fluid within the lumen to exit and when the fluid pressure outside the catheter exceeds the fluid

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pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen.

References Cited by the Examiner:

Eaton	US 3,303,847	Feb. 14, 1967
Yamauchi	US 3,718,140	Feb. 27, 1973
Engelson	US 5,789,018	Aug. 4, 1998

Grounds of Rejection

1. Claims 43, 44 and 61 stand rejected under 35 U.S.C. § 102(b), over Eaton.
2. Claims 43, 44 and 46 stand rejected under 35 U.S.C. § 102(b), over Yamauchi.
3. Claims 45 stands rejected under 35 U.S.C. § 103(a), over Eaton in view of Engelson.
4. Claim 46 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Eaton in view of Yamauchi.

DISCUSSION

Background

“The invention generally relates to medical infusion and aspiration of fluids through a catheter, and in particular to improved catheter slit valves for medical fluid infusion and aspiration.” (Spec. 1.) “The improved catheter slit valves of the invention use nonradial slits to address the problems found with conventional radial slit valves, e.g., difficulty in aspiration. The nonradial slit valves are more efficient than radial slit,

valves, because the geometry of the nonradial slit allows the catheter material to move apart with less interference or friction from the opposing wall. For example, the nonradial slit allows for easier aspiration by reducing the pressure required to open the valve, because less displacement of the wall is required to move the adjacent wall segments apart.” (Spec. 2.)

The term “catheter” is not defined in the Specification. The *American Heritage Science Dictionary* (2005) defines the term “catheter” as “[a] hollow, flexible tube inserted into a body cavity, duct or vessel to allow the passage of fluids or distend a passageway.”

1. Claims 43, 44 and 61 stand rejected under 35 U.S.C. § 102(b), over Eaton. We select claims 43 and 61 as representative of the rejection before us since Appellants have not separately argued claim 43. 37 C.F.R. 41.37(c)(1)(vii).

The Examiner contends and finds that

Eaton discloses a medical device having an elongate catheter (5) with an external surface and an internal surface defining an internal lumen and having a compound slit (8, 9) located at a generally hemispherical distal end portion (6) of the catheter and extending from the external surface to the internal surface (see Fig. 4).

The slit of Eaton is biased closed and opens due to difference in pressure between the lumen and the ambient. The slit of Eaton is also configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference between the pressure ambient pressure and the pressure inside the lumen and to flex outward when the internal pressure exceeds the external pressure by a second amount.

(Ans. 3.)

Appellants contend that a direct statement in Eaton indicates that the slits part slightly when the container is squeezed and thus Eaton describes a mechanical deformation of the valve due to squeezing and not any fluid pressure activated valve behavior. (Reply Brief 3.) The Appellants further argue that Eaton nowhere implies that fluid pressure is used to part the slits. (Reply Br. 3.)

Therefore, the issue is whether Eaton teaches a compound slit opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter, as claimed.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). As stated *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (CCPA 1939)) (internal citations omitted):

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. *In re Oelrich, supra; Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Under the principles of inherency, if the prior art

necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986).

We agree with the Examiner that the disposable container of Eaton for dispensing of liquid materials inherently allows a compound slit to open in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter. For example, Eaton indicates that “slight pressure applied to the body portion will cause the slits or cuts 8 and 9 of the flexible catheter to part slightly, the opening serving as a sort of spray nozzle.” (Eaton, col. 3, ll. 65-70.) “[W]hen the container is not subjected to pressure the opening will remain closed sufficiently tightly to retain the contents of the container-applicator against the force of gravity.” (Eaton, col. 3, ll. 70 to col. 4, ll. 1.) Therefore, upon manual pressure to the fluid or cream inside the container of Eaton, the fluid pressure causes the slits of the catheter to part. Because the container of Eaton may contain a fluid, the compound slit inherently opens in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter. Thus, we are not convinced by Appellants argument and find that Eaton anticipates claim 43.

Appellants provide separate argument for claim 61, and therefore we address this claim separately.

The Examiner contends that “the flaps of Eaton would indeed flex inwardly if there was a pressure differential as claimed.” (Ans. 5.) Appellants contend that Eaton fails to teach the claim limitation wherein “when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen.” (Br. 10.)

Again, Eaton indicates that “slight pressure applied to the body portion will cause the slits or cuts 8 and 9 of the flexible catheter to part slightly, the opening serving as a sort of spray nozzle.” (Eaton, col. 3, ll. 65-70.) When the container is not subjected to pressure the opening will remain closed sufficiently tightly to retain the contents of the container-applicator against the force of gravity. (Eaton, col. 3, ll. 70 to col. 4, ll. 1.) We find from this disclosure that one of ordinary skill in the art would understand that Eaton inherently discloses the corollary, that when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen, the slits flex into the lumen to allow fluid outside the catheter to enter the lumen. Furthermore, Eaton discloses that the cover member 10 “will be characterized by flexibility and some elasticity” (Eaton, col. 4, ll. 24-27) evidencing that the slits would be capable of flexing into the lumen to allow fluid outside the catheter to enter the lumen in the presence of an ambient pressure differential.

In view of the above, the rejection of claim 61 is affirmed.

2. Claims 43, 44 and 46 stand rejected under 35 U.S.C. § 102(b), over Yamauchi. We select claim 43 as representative of the rejection before us since Appellants have not separately argued the claims. 37 C.F.R. 41.37(c)(1)(vii).

The Examiner finds that

Yamauchi discloses a medical device having an elongate catheter with an external surface and an internal surface defining an internal lumen and having a compound slit (6) located at a generally hemispherical distal end portion of the catheter and extending from the external surface to the internal surface (see Fig. 3). The slit of Yamauchi is biased closed and

opens due to difference in pressure between the lumen and the ambient. The slit of Yamauchi is also configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference between ambient pressure and the pressure inside the lumen and to flex outward when the internal pressure exceeds the external pressure by a second amount.

(Ans. 3.)

Appellants contend that “Yamanouchi does not disclose or suggest ‘an elongate catheter,’ as recited in claim 43.” (Br. 15.) Appellants further argue that Yamanouchi “a compound slit ‘opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,’” as recited in claim 43. (Br. 16.)

The issue before is whether Yamanouchi discloses an elongate catheter and “a compound slit … opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,” as recited in claim 43.

As recognized by the Examiner, Yamanouchi discloses a “tubular device that is inserted into a body cavity (mouth) to inject fluids (milk)”. (Ans. 5.) Thus, we agree with the Examiner that Yamanouchi discloses a catheter consistent with the definition of catheter set forth in the Background section herein. Yamanouchi further discloses that the nipple outlet can be readily opened when subjected to suction externally exerted thereon. (Yamanouchi, col. 2, ll. 61-65.) The external suction creates a pressure gradient which allows the internal fluid subjected to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter to

open the nipple outlet. Thus, we find that Yamanouchi discloses an elongate catheter having “a compound slit … opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,” as recited in claim 43.

We are not persuaded by Appellants argument and the rejection over Yamanouchi is affirmed.

3. Claims 45 stands rejected under 35 U.S.C. § 103(a), over Eaton in view of Engelson.

The Examiner acknowledges that Eaton fails to disclose the collar of claim 45. Therefore, the Examiner relies on Engelson for the disclosure of a collar (130) used on a similar catheter. (Ans. 5.) The Examiner concludes, “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the collar of Engelson et al. with the catheter of Eaton so that the catheter can be radiographed visually as taught by Engelson et al.” (Ans. 4.)

Appellants contend that “because claim 45 depends from, and, therefore includes all the elements recited in claim 43, … that neither Eaton nor Engelson,discloses or suggests the subject matter of claim 45. (Br. 17.) As discussed herein, we have found that claim 43 is anticipated by the disclosure of Eaton. Appellants have failed to provide specific rebuttal argument to the collar recited in claim 45.

In view of the above, we affirm the rejection of claim 45 over Eaton in view of Engelson.

4. Claim 46 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Eaton in view of Yamauchi.

The Examiner finds that

Eaton fails to disclose wherein the compound slit is a tricuspid slit. Yamauchi discloses the tricuspid slit (Y) in Figure 5 and further the cross-shaped slit in Figure 2 which is equivalent to the slit shown by Eaton.

It would have been obvious to one having ordinary skill in the art to utilize the tricuspid slit of Yamauchi in place of the cross-shaped slit of Eaton since Yamauchi discloses the equivalence of the tricuspid and cross-shaped slits.

(Ans. 5.)

Appellants argue that “because claim 45 depends from, and therefore includes all the elements recited in claim 43, ... that neither Eaton nor Yamauchi, ... discloses or suggests the subject matter of claim 45. (Reply Br. 7.) As discussed herein, we have found that claim 43 is anticipated by the disclosure of Eaton. Appellants have failed to provide specific rebuttal argument to the tricuspid slit recited in claim 45.

In view of the above, we affirm the rejection of claim 45 over Eaton in view of Yamanouchi.

SUMMARY

The rejections of the claims for anticipation and obviousness are affirmed.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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